510(k): K102614

JUN - 3 2011

**Bio-Medical Research Ltd.**
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This 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

## 1. Contact Details

| | |
|---|---|
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| Prepared: | April 22, 2011 |

## 2. Device Name

| | |
|---|---|
| Trade Names of Devices: | AvivaFix Conductive Garment – Knee, Type 420 |
| | AvivaFix Conductive Garment – Shoulder, Type 420 |
| | AvivaFix Conductive Garment – Upper Back, Type 420 |
| Common Name: | Cutaneous Electrode |
| Classification: | Class II |
| Product Code: | GXY |

## 3. Identification of Equivalent Legally Marketed Devices

| | |
|---|---|
| Device Trade Name: | Lumbofix Conductive Garment, Type 420 Back |
| Manufacturer: | Bio-Medical Research Ltd |
| 510(k) No: | K091317 |
| | |
| Device Trade Name: | Kneehab XP Conductive Garment, Type 411 |
| Manufacturer: | Bio-Medical Research Ltd |

## 4. Description of Device

The AvivaFix Conductive Garment – Knee, AvivaFix Conductive Garment – Shoulder, and AvivaFix Conductive Garment - Upper Back (all Type 420) are intended for use in conjunction with transcutaneous electrical nerve stimulation (TENS) and neuromuscular electrical stimulation (NMES). The garments aid in the placement of electrodes and secure the electrodes in place. The inner layer of the garment is constructed of Breathoprene", which is a breathable, stretchable fabric developed by AccuMed Technologies as a neoprene substitute to keep skin cooler and drier by wicking away perspiration.

## 5. Indications for Use

The AvivaFix Conductive Garment – Knee, AvivaFix Conductive Garment – Shoulder, and AvivaFix Conductive Garment - Upper Back (all Type 420) are intended for use with Neurotech Stimulator devices. It is intended to aid in the repeatable placement of electrodes (under the guidance of a clinician) and to secure them in place.

The AvivaFix Conductive Garment – Knee, AvivaFix Conductive Garment – Shoulder, and AvivaFix Conductive Garment - Upper Back (all Type 420) also maintain a level of compression in the areas of electrode placement to maintain electrode placement during treatment.

The AvivaFix Conductive Garment – Knee, Type 420 is intended for use on the knee.
The AvivaFix Conductive Garment – Shoulder, Type 420 is intended for use on the shoulder.
The AvivaFix Conductive Garment - Upper Back, Type 420 is intended for use on the upper back (cervical) area.

The AvivaFix Conductive Garment – Knee, AvivaFix Conductive Garment – Shoulder and AvivaFix Conductive Garment - Upper Back (all Type 420) devices and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the shoulder, knee and upper back (cervical) areas.

## 6. Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the AvivaFix Conductive Garments. Substantial Equivalence has been demonstrated as part this 510k submission.

## 7. Clinical and Non-Clinical Tests

No new clinical studies have been submitted as part of this premarket notification.

The AvivaFix Conductive Garments (Knee, Shoulder and Upper Back) complies with the following standards:

- 21 CFR 898 Performance standard for electrode lead wires and patient cables
- ISO 14971:2007 Medical Devices – Application of risk management to medical devices
- ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2002/Amd. 1:2006 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Bio-Medical Research, Ltd.
c/o Ms. Anne-Marie Keenan
Quality / Regulatory Affairs Engineer
Parkmore Business Park West
Galway, Ireland

JUN - 3 2011

Re: K102614
Trade/Device Names: AvivaFix Conductive Garment Knee Type 420, AvivaFix Conductive Garment Upper Back Type 420, AvivaFix Conductive Garment Shoulder Type 420
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: May 25, 2011
Received: May 31, 2011

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah Falls

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K102614

**Device Names:**

AvivaFix Conductive Garment – Knee, Type 420
AvivaFix Conductive Garment – Shoulder, Type 420
AvivaFix Conductive Garment – Upper Back, Type 420

**Indications for Use:**

The AvivaFix Conductive Garment – Knee, AvivaFix Conductive Garment – Shoulder, and AvivaFix Conductive Garment - Upper Back (all Type 420) devices are intended for use with Neurotech Stimulator devices. It is intended to aid in the repeatable placement of electrodes (under the guidance of a clinician) and secure them in place.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102614